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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,755	03/23/2001	Nagarajan Vaidehi	06618-606001/CIT3191	4783
26181	7590	09/29/2005	EXAMINER	
FISH & RICHARDSON P.C.			MILLER, MARINA I	
PO BOX 1022			ART UNIT	
MINNEAPOLIS, MN 55440-1022			PAPER NUMBER	

1631

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/816,755

Applicant(s)

VAIDEHI ET AL.

Examiner

Marina Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 35-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 35-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicants' submission filed on 7/15/2005 is acknowledged. Claims 1, 3, and 35-58 are pending. Claims 2 and 4-34 are cancelled. Claims 1, 3, and 35-58 presently are under examination.

Applicants' arguments have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are applied.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 36-38, 41-42, 44-46, 48, and 51-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Biggin, *Biophysical Chemistry*, 76:161-183 (1999).

Biggin discloses modeling and simulation studies of membrane proteins comprising steps of providing an amino acid sequence for a membrane-bound protein, identifying a range or ranges of amino acids as transmembrane regions, constructing helices, optimizing a helix bundle configuration, constructing inter-helical loops to generate a full-atom model, optimizing the full-atom model, and outputting a predicted structure, as set forth in the previous office action mailed 1/14/2005.

Applicants argue that Biggin does not disclose a method for predicting a structure of a membrane-bound protein, but discloses computer simulation studies of helix/bilayers interactions

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which is allegedly different from the instant method of predicting a structure (p. 16 of applicants' response filed 7/15/2005).

Applicants' arguments have been considered but are not found persuasive.

Biggin's method simulates a membrane-bound protein structure in various environments (*e.g.*, water, phospholipids, with/without a bilayer, solvated bilayer, *etc.*) (*see*, for example, p. 162, left col. and p. 171). The instant method also simulates a membrane-bound protein structure in an environment (water or lipid bilayer) (*see* instant claim 46 and the specification p. 14, line 6-9 and fig. 4, step 460). Biggin teaches "modeling and simulation studies of membrane proteins and of their interactions with lipid bilayer" (*i.e.*, modeling of both membrane proteins and interaction of proteins with a membrane) (p. 162, left col.). Biggin discloses a two-stage model of membrane protein folding (p. 162, right col.). Biggin states that "simulation studies of TM helices and TM helix bundles will help us to understand the principles of the structure" (p. 165, left col.). Biggin discloses that several algorithms exist for predicting of the number and position of TM helices within a membrane protein sequence (p. 174). Further, Biggin states that MD simulations of model TM helices may be used to refine the results of such prediction (p. 174). Biggin illustrates the refinement on M2 protein from influenza wherein TM helices were simulated (p. 174). Biggin discloses a helix bundle simulation in a POPC bilayer (fig. 9). Thus, Biggin does provide for a method of simulation similar to the instant method. For the reasons stated above, the rejection of claims 1, 36-38, 41-42, 44-46, 48, and 51-58 under 35 U.S.C. 102(b) over Biggin is maintained.

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biggin, *Biophysical Chemistry*, 76:161-183 (1999), as applied to claims 1, 36-38, 41-42, 44-46, 48, and 51-58, in view of Rose, U.S. Patent 5,680,319.

Claims 39, 40, 49, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biggin, *Biophysical Chemistry*, 76:161-183 (1999), as applied to claims 1, 36-38, 41-42, 44-46, 48, and 51-58, in view of Mathiowetz, *Proteins: Structure, Function, and Genetics*, 20:227-247 (1994).

Claim 47 is are rejected under 35 U.S.C. 103(a) as being unpatentable over Biggin, *Biophysical Chemistry*, 76:161-183 (1999), as applied to claims 1, 36-38, 41-42, 44-46, 48, and 51-58, in view of Mayo, J. Phys. Chem., 94:8897-8909 (1990).

As the rejection set forth above over Biggin with regard to claims 1, 36-38, 41-42, 44-46, 48, and 51-58 is maintained, the rejection of claims 3, 35, 39, 40, 47, 49, and 50 under 35 U.S.C. 103(a) set forth in the previous office action mailed 1/14/2005 is also maintained.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-5, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph. D. can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**MARJORIE A. MORAN**  
**PRIMARY EXAMINER**

*Marjorie A. Moran*  
9/15/05

Marina Miller  
Examiner  
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